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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,308	09/12/2005	John Nieland	50402/002002	6391

21559 7590 04/11/2008

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
04/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/528,308	NIELAND ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 22 and 40 - 47* is/are pending in the application.

4a) Of the above claim(s) *6 - 15, 18, 19, 40 -47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 5, 16, 17, and 20 - 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/7/07; 1/25/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1 – 22, and the species 2-(6-(4-chlorophenoxy)hexyl)oxirane-2- carboxylic acid ethyl ester (Etomoxir) as the inhibitor of fatty acid oxidation; inhibits Carnitine-Palmitoyl-Transferase-1 (CPT-1) as the effect of the inhibitor; psoriasis as the disease or disorder; and administration of the inhibitor without combination with further therapy in the reply filed on January 25, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because of the following informalities: the Brief Description of the Drawings is the last section of the specification, after the Detailed Description of the Invention so the arrangement of the specification does not match the preferred arrangement shown below.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

3. Claim 3 is objected to because of the following informalities: the name of the chemical compound "carnitine" has been misspelled and appears as "carnitin".

Appropriate correction is required.

Claim Rejections - 35 USC § 112 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. None of the derivatives meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. While examples of preferred derivatives are provided on p 7, ln 10 – 12, the compounds described are encompassed by formula I. The specification provides insufficient written description to support the genus of derivatives encompassed by the claim, since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a derivative.

6. Claims 1 – 5, 16, 17 and 20 – 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of a chronic and/or an atopic skin disease, does not reasonably provide enablement for the

prevention of a chronic and/or an atopic skin disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure and claims of the application have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation

The factors include:

1. The nature of the invention;
2. The breadth of the claims;
3. The predictability or unpredictability of the art;
4. The amount of direction or guidance presented;
5. The presence or absence of working examples
6. The quantity of experimentation necessary;
7. The state of the prior art; and
8. The relative skill of those skilled in the art.

Each factor is address below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1. The nature of the invention: a method of preventing and/or treating a chronic and/or an atopic skin disease with an inhibitor of fatty acid oxidation in a pharmacologically effective amount.

2. The breadth of the claims: A variety of inhibitors (small molecules such as those described by formula I, antisense oligonucleotides, ribozymes and dsRNA) are contemplated for use in this method. A number of skin conditions are also contemplated (see claim 16).

3. The amount of direction or guidance presented, the presence or absence of working examples: experiments involving tissue culture cells, mice and human skin transplanted on mice and treated with etomoxir are presented.

4. The predictability or unpredictability of the art, the quantity of experimentation necessary, the state of the prior art, and the relative skill of those skilled in the art: The relative skill of those skilled in the art is high. "Prevent" (dictionary.com, accessed 11/27/07) is defined as to stop, to keep from happening or arising or make impossible (p 3). There is no indication, either in the prior art or in the examples presented by Applicant, that administration of an inhibitor fatty acid oxidation will mean that an subject will never develop a chronic and/or an atopic skin disease such as psoriasis. Therefore, Applicant is enabled for the treatment of a chronic and/or an atopic skin disease with an inhibitor of fatty acid oxidation such as etomoxir but is not enabled for the prevention of a chronic and/or an atopic skin disease.

Claim Rejections - 35 USC § 112 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "predominantly fluorine-substituted" in the definition of R2 and R4 is a relative term which renders the claim indefinite. The term "predominantly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

9. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a

required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 16 recites the broad recitation cutaneous atopy, and the claim also recites eczema, which is the narrower statement of the limitation. Claim 16 also recites the broad recitation pigmentation disorders, and recites hyperpigmentation, melasma, hypopigmentation and vitiligo, which are narrower statement of the limitation "hyperpigmentation disorders".

10. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

11. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 contains the trademark/trade name Vaseline. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used

properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe petroleum jelly and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 16, 17 and 20 – 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Marshall et al. (US Patent 4,933,365, entire document, cited on PTO-1449).

Marshall et al. discloses compounds that are inhibitors of fatty acid oxidation (col 3, ln 32 – 59) and the PLA_2 enzyme (col 7, ln 50). As such, they are useful in the treatment of conditions mediated by products of the oxidation of arachidonic acid (col 7, ln 49 – 52) such a psoriasis and related skin inflammation (col 7, ln 59 – 60). The compounds may or may not combined with other carriers (col 8, ln 36 – 37). They can be applied topically and formulated as dusting powders, cream or lotion in

pharmaceutically acceptable vehicles which are applied to the affected portion of the skin (col 8, ln 48 – 52).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1 – 5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen et al. (J Invest Dermatol 1992) in view of Spurway et al. (FEBS Letters, 1997).

Madsen et al. discloses that psoriatic keratinocytes contain dramatically upregulated levels of PA-FABP (psoriasis-associated fatty acid binding protein), as well as increased levels of total lipids, phospholipids, free arachidonic acid and derivatives of arachidonic acid such as leukotrienes (p 304, col 2, paragraph 1). The proteins such as PA-FABP and others up-regulated in psoriatic tissue are only minor components of normal skin (p 304, col 2, paragraph 2). These observations were made in human skin cells (p 300, col 1, paragraph 2). Taken together, these data indicate that altered transport and/or metabolism of fatty acids are involved in psoriasis (p 304, col 2, paragraph 1).

Madsen et al. does not disclose the use of etomoxir in treating psoriasis.

Spurway et al. discloses that etomoxir is an inhibitor of mitochondrial long-chain fatty acid oxidation (abstract, p 111, col 1, paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use etomoxir, taught by Spurway et al. as a inhibitor of fatty acid oxidation, in a method of treating a psoriasis, a disease associated with altered fatty acid transport and/or metabolism (as taught by Madsen et al.).

18. Claims 17 and 20 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen et al. and Spurway et al. as applied to claims 1 – 5 and 16 above, and further in view of Marshall et al. (US Patent 4,933,365).

As discussed above, Madsen et al. and Spurway et al. disclose alterations in fatty acid metabolism and/or transport which occur in psoriatic skin and that etomoxir is inhibitor of long-chain fatty acid oxidation.

Madsen et al. and Spurway et al. do not teach topical administration of the compound to treat psoriasis nor the administration of the compound together with at least one excipient and/or auxiliary.

Marshall et al. discloses methods for the treatment of inflammatory disorders such as psoriasis using compounds that inhibit phospholipase A_2 (col 7, ln 49 – 52, 59 – 60). The compounds may or may not combined with other carriers (col 8, ln 36 – 37). They can be applied topically and formulated as dusting powders, cream or lotion in pharmaceutically acceptable vehicles which are applied to the affected portion of the skin (col 8, ln 48 – 52).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a topical application, optionally in combination with carriers as taught by Marshall et al., to deliver the etomoxir active ingredient in a method of treating psoriasis, as taught by Madsen et al. and Spurway et al. as both Marshall et al. and the combination of Madsen et al. and Spurway et al. relate to methods of delivering an active agent in a method for treating psoriasis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW